DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1763d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

SEP 25 2001

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Kai Hansjurgens
President
Hako-Med Electromedicine, Incorporated
537 Cummins Street
Honolulu, Hawaii 96814

Re: ElecDT Horizon, ProElecDT Horizon,
ProElecDT 2000, ElecDT, ProElecDT;
K980892, K980958

Dear Mr. Hansjurgens:

We are writing to advise you of continuing regulatory problems involving the ElecDT Horizon, ProElecDT Horizon, ProElecDT 2000, ElecDT, and ProElecDT devices being marketed by your company. These products are manufactured by Hako-Med Electromedicine, Incorporated (Hako-Med), distributed by Alive, Incorporated (Alive), and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Both the ElectDT and ProElectDT are Interferential Current Therapy devices (Product Code 84 LIH) that were cleared under section 510(k) of the Act, and are intended for: adjunctive use in post-traumatic pain syndromes; the management and symptomatic relief of chronic (long-term) pain; adjunctive treatment in the management of post-surgical pain problems; relaxation of muscle spasms; prevention or retardation of disuse atrophy; temporary increases in local blood circulation; muscle re-education; immediate post surgical stimulation of calf muscles to prevent venous thrombosis; and, for maintaining or increasing range of motion.

On May 12 1999, the Promotion and Advertising Policy Staff (PAPS), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) sent you a letter requesting copies of your current labeling and promotional materials for the ElecDT Horizon, ProElecDT 2000, ElecDT, and ProElecDT devices. Later that month, we received a response from Mr. Blair Collins, Operations Manager for Alive, Incorporated, which included various brochures, instruction manuals, flyers, bulk mailings, and promotional folders for these devices. Following our review of these materials, we issued a letter to your company on June 18, 1999 advising you that many of the claims appearing in these promotional materials had not been cleared by the agency. We asked for a prompt written response, but no response was received.

On May 7 2001, we sent a letter addressing the same issues and again, we did not receive a response. On

July 2, 2001 you spoke with Mr. Steven E. Budabin of our office, who requested that you provide a status report. At that time you indicated a response would be forthcoming in the near future. However, we have no record of a response.

ElecDT and ProElecDT:

We have re-reviewed two of your web sites at the Internet addresses: http://www.hakomed.com and http://www.electromedicine.com. As of September 25, 2001 portions of these web sites continue to include the phrase "complex acute and chronic pain conditions" (chronic pain is cleared but complex acute and chronic pain are not). Additionally, your web sites contain an incorrect phrase for one of the intended uses: "Prevention or retardation of tissue atrophy" (the correct phrase is disuse atrophy).

Marketing the ElecDT and ProElecDT Interferential Current Therapy devices for claims of complex acute and chronic pain causes these devices to be misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii) and section 510(k) of the Act, and the devices were not found to be substantially equivalent to a predicate device.

The ElecDT and ProElecDT are also adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have in effect either approved applications for premarket approval (PMA) pursuant to section 515(a), or approved applications for investigational device exemption (IDE) under section 520(g).

ElecDT Horizon, ProElecDT Horizon, and ProElecDT 2000

The agency has no record to indicate that these devices have been cleared for marketing. If the ElectDT Horizon, the ProElecDT Horizon, and the ProElectDT 2000 represent either new devices or significant modifications in the intended use(s) of the ElecDT and/or ProElecDT devices respectively, as described under the provisions of 21 CFR 807.81(a)(3)(ii), and in FDA's January 10, 1997, guidance document titled, Deciding When to Submit a 510(k) for a Change to an Existing Device, then they cannot be marketed until these requirements have been satisfied.

Representative examples of claims for the ElecDT Horizon, ProElecDT Horizon, and ProElecDT 2000 appearing on both of your web sites include, but are not limited to the following:

> -On the page titled, "The Cutting Edge of Pain Management Technology"..."At Hako-Med, our challenge is to help today's medical professional treat...circulatory disorders in new ways with products that provide consistent, effective results"
>
> -"For a limited time, Hako-Med is introducing the ProElecDT Horizon, a preprogrammed clinical bioelectric delivery system for the treatment of acute and chronic pain and circulatory disorders..." (Circulatory disorders are not cleared)
>
> -"Muscle rehabilitation"
>
> -"Complex acute and chronic pain conditions" (chronic pain is cleared)

-"Prevention or retardation of tissue atrophy" (the correct word should be disuse atrophy)

-"Our groundbreaking device (ElecDT Horizon) offers the modern practice the latest in electromedical technology. Its' internationally patented horizontal therapy form delivers both stimulatory class and middle frequency class effects in the same area simultaneously"

The ElecDT Horizon, the ProElecDT Horizon, and the ProElecDT 2000 are misbranded within the meaning of section 502(o) in that a notice or other information respecting the devices was not provided to FDA as required by section 510(k).

The ElecDT Horizon, the ProElecDT Horizon, and the ProElecDT 2000 are also adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have in effect either approved applications for premarket approval (PMA) pursuant to section 515(a), or approved applications for investigational device exemption (IDE) under section 520(g).

Furthermore, on your web page titled, General Information about Electromedicine, Hako-Med states, "Today, hundreds of doctors and medical researchers worldwide are investigating electromedicine as both an effective alternative to traditional methods of treatment and an avenue for discovering new possibilities for treating conditions such as spinal cord injury, muscular restoration, nerve regeneration, brain stimulation, bladder disorders, heart disease, tumors and other chronic catastrophic disorders. Because these conditions appear on the same web site as your cleared devices (ElecDT and ProElecDT), this discussion implies that your electromedicine devices may be used to treat the conditions you have listed. None of these conditions has been cleared for use with your devices.

Additionally, we note that both your web sites make claims for the mechanism of action of your devices such as: anti-inflammatory action, edema management, regeneration activation and support, muscle activation and facilitation, immune system support, facilitation of metabolism, and influence on metabolism. Please provide the requisite data to this office in support of the mechanisms of action identified above (the type of data to provide may include clinical studies, peer-reviewed journal reprints, or other data).

Our review of your 1999 and early 2001 promotional materials included the following claims:

For the ElecDT and ProElecDT:

-Treatment of conditions such as spinal cord injury, nerve regeneration, brain stimulation, bladder disorders, heart disease, tumors and other chronic catastrophic disorders, inflammatory, obstructive, vasospastic, and/or generalized edema (electromedicine.com web site, June 1999).

-Claims that your devices can block pain in peripheral nerves i.e., nerve block i.e., "Pain fiber block (Gildemeister et. al) Peripheral block of pain conducting fibers in the effective range of higher intensities of non-modulated middle frequency even by reactive depolarization with plateau formation." (from the electromedicine.com web site section titled, Use of the Stimulatory and the Middle Frequency Effects. (June 1999)

For the ElecDT Horizon and ProElecDT 2000:

-Whole body treatment; Achilles tendonitis; calcanear apophysitis; retrocalcaneal subtendonitis; bursal syndromes; acute humeroscapular peri-arthritis; allergic conjunctivitis; arterial hypertension; atonic constipation; atypical facial neuralgia; Bell's palsy; bronchial asthma; cervical fibrositis; trigger points; myogelosis; fibromyositis; chronic cystitis; chronic cystopyelitis; chronic cystoplelonephritis; chronic frontal sinusitis; diabetic angiopathies; arterial occlusive disease; extended hematoma – in the calf region and a beginning compartment syndrome; fractures; gout; gout nodes; hyperuricaemic arthritis; lymphedema of the upper limbs; migraine during an attack or during a symptom-free interval; motor neuron disease; muscular hypertension on the dorso-lateral neck region; osteoarthritis in the ankle, carpal, hip, knee, or shoulder joint, including frozen shoulder; osteoporosis; patellofemoral pain syndrome; polyneuropathy; post-surgical atony following abdominal surgery; post traumatic edema; radiation damages including dermatitis, fibrosis, necrosis, and/or ulcer; reflex sympathetic dystrophy (RSD); Raynaud's disease; shoulder pain and shoulder stiffness in cases of hemiplegia; sprains, strains, distortions, contusions and bruises in the elbow joint, shoulder, ankle, knee, or wrist; spastic constipation; subcutaneous hematoma in the calf; tennis elbow – lateral epicondylitis; tension headaches; and trigeminal neuralgia

-Edema reduction, vasoconstriction, activation of muscle pump, sympathetic function fatigue, activation of lipolysis, prevention of thrombosis, muscle strengthening/endurance, influence of metabolism, myofascitis, mycid, non-infectious inflammations, wounds, rheumatoid arthritis, sciatica, angiopathy, ankylosing spondylitis, cerviobrachial syndromes, shoulder girdle, and reinnervation acceleration, and Reflex Sympathetic Dystrophy (RSD)

-In a chart titled, "Electrical Differentiation in Treatment (EDT)"... circulatory and lymphatic influence, edema reduction, reinnervation acceleration, influence on metabolism, anti-inflammatory action, regeneration activation and support, immune system support (Cell Communication), facilitation of metabolism, tendonitis, epicondylitis, lumbago, sciatica, Bell's Palsy, muscle rehabilitation and strengthening, knee joint disorders, mycid, distortions, ankylosing spondylitis, shoulder syndromes, cerviobrachial syndromes, constipation, shoulder girdle, chronic polyarthritis, neuralgia, neuroma, inflammations (non-infectious), severe pain, wounds, severe neurogenic pain, rheumatoid arthritis, fractures, sciatica, polyneuropathy, angiopathy, and myofascitis

-Page titled, "Stimulatory Class (A)"...circulatory and lymphatic influence, edema reduction, reinnervation acceleration, imitative action, thrombosis prevention, endurance training, muscle strengthening, influence on metabolism

-Page titled, "Multi-Facilitory Class (B)"...circulatory and lymphatic influence, anti-inflammatory action, edema reduction, regeneration activation and support, immune system support, facilitation of metabolism

We have also previously reviewed a Hako-Med videotape, which was allegedly distributed to physicians at various conferences in the United States. The video shows how three patients were treated with Hako-Med devices for osteoarthritis: an 80 year old women with osteoarthritis of the knee; a 61 year old male with arthritis of his shoulder; and, a 65 year old female with arthritis of the left knee. All patients were treated with horizontal therapy for 40-60 minutes.

We remind Hako-Med that you may not promote your devices for any claims without first obtaining prior marketing clearance via either a 510(k) or PMA. This prohibition would also apply to workshops,

seminars, hands-on demonstrations, or videotapes produced by Hako-Med or on behalf of Hako-Med. This letter is not intended to be an all-inclusive list of deficiencies associated with your ElecDT and ProElecDT devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Additionally, we ask that Hako-Med address the issues related to the ElecDT Horizon, ProElecDT Horizon, and the ProElecDT 2000.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health